DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 17, 2015

Stryker Orthopaedics
Ms. Denise Daugert
Senior Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K143085
Trade/Device Name: Stryker Orthopaedics Acetabular Shells, Femoral Stems and Total Hip Instruments for Use with the Direct Superior Approach
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI, KWL, KWY, KWZ, LWJ, LZO, MAY, MBL, MEH
Dated: November 11, 2014
Received: November 12, 2014

Dear Ms. Daugert:

This letter corrects our substantially equivalent letter of February 9, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K143085

Device Name: Stryker Orthopaedics Acetabular Shells, Femoral Stems and Total Hip Instruments for use with the Direct Superior Approach.

Trident PSL Shell, Trident Tritanium Shell, Trident Hemispherical Shell

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

The Trident shells are intended for cementless fixation within the prepared acetabulum.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K143085

Device Name: Stryker Orthopaedics Acetabular Shells, Femoral Stems and Total Hip Instruments for use with the Direct Superior Approach.

Tritanium Acetabular Shell System

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

The Tritanium Acetabular Shell System is intended for cementless use only.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K143085

Device Name: Stryker Orthopaedics Acetabular Shells, Femoral Stems and Total Hip Instruments for use with the Direct Superior Approach.

Accolade II Femoral Stem

The indications for use for total hip arthroplasty with stems include:

- noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of the Accolade II Femoral Stem with compatible Howmedica Osteonics Constrained Liners:

- When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

Accolade II Femoral Stems are intended for cementless use only and are intended for total and hemiarthroplasty.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K143085

Device Name: Stryker Orthopaedics Acetabular Shells, Femoral Stems and Total Hip Instruments for use with the Direct Superior Approach.

Secur-Fit Advanced Hip Stem

The indications for use for total hip arthroplasty with stems include:

- noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of Secur-Fit Advanced Hip Stems with compatible Howmedica Osteonics Constrained Liners:

- When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

Secur-Fit Advanced Hip Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K143085

Device Name: Stryker Orthopaedics Acetabular Shells, Femoral Stems and Total Hip Instruments for use with the Direct Superior Approach.

Anato Hip Stem

The indications for use for total hip arthroplasty with stems include:

- noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of Anato Hip Stem with compatible Howmedica Osteonics Constrained Liners:

- When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

The Anato Hip Stem is intended for cementless use only and is intended for total and hemiarthroplasty procedures.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Sponsor

Stryker Orthopaedics
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Contact Person

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Date Prepared: October 23, 2014

Proprietary Name: Stryker Orthopaedics Acetabular Shells, Femoral Stems and Total Hip Instruments for use with the Direct Superior Approach

Common Name: Total Hip Joint Replacement

Classification Name:

Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (888.3358)
Hip joint Metal/Ceramic/Polymer Semi-Constrained Cemented or Non Porous Uncemented Prosthesis (888.3353)
Hip joint metal/polymer semi-constrained cemented prosthesis (888.3350)
Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (888.3390)
Hip joint metal/polymer constrained cemented or uncemented prosthesis (888.3310)
Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (888.3360)

Product Codes: 87LPH, 87 MEH, 87LZO, 87MBL, 87MAY
87LWJ, 87KWZ, 87KWY, 87KWL, 87JD1

Legally Marketed Device to Which Substantial Equivalence is claimed:

Trident PSL Shell (K983382)

Trident Tritanium Shell (K010170)

Trident Hemispherical Shells (K013676)

Tritanium Acetabular Shell System (K081171)

Accolade II Femoral Stem (K120578)

Secur-Fit Advanced Stem (K122853)

Anato Hip Stem (K123604)

Device Description:

The devices covered by this submission include Stryker Orthopaedics Acetabular Shells, Femoral Stems and Total Hip Instruments. The Instruments consist of Retractors, Cup Impactors, U-Joint Bolt Driver, Alignment Guide, Angled Reamer Handle, Instrument Trays and a Case. All instruments are hand-held surgical instruments used during orthopaedic surgery and are non-sterile, reusable devices. All Class II devices in this submission have been previously determined substantially equivalent in prior 510(k) submissions and are commercially available. The acetabular shells and femoral stems are manufactured from the following materials: titanium (Ti-6Al-4V) alloy, commercially pure (CP) titanium plasma spray, commercially pure titanium and PureFix® hydroxylapatite (HA).

Intended Use:

The Stryker Orthopaedic Acetabular Shells for use with the Total Hip Instruments are intended for use in total hip arthroplasty and are intended for either primary or revision total hip arthroplasty. The Stryker Orthopaedic Hip Implant Stems for use with the Total Hip Instruments are intended for use in total or hemi-arthroplasty of the hip and are intended for either primary or revision procedures. The Direct Superior Approach does not change the intended use of the subject devices.

Indications for Use (Trident PSL Shell, Trident Tritanium Shell, Trident Hemispherical Shells):

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

The Trident shells are intended for cementless fixation within the prepared acetabulum.

Indications for Use (Tritanium Acetabular Shell System):

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

The Tritanium Acetabular Shell System is intended for cementless use only.

Indications for Use (Accolade II Femoral Stem):

The indications for use for total hip arthroplasty with stems include:

- Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;

- Revision procedures where other treatments or devices have failed; and,
- Nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of the Accolade II Femoral Stems with compatible Howmedica Osteonics Constrained Liners:

- When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

Accolade II Femoral Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

Indications for Use (Secur-Fit Advanced Hip Stem):

The indications for use for total hip arthroplasty with stems include:

- Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and,
- Nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of the Secur-Fit Advanced Hip Stems with compatible Howmedica Osteonics Constrained Liners:

- When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

Secur-Fit Advanced Hip Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

Indications for Use (Anato Hip Stem):

The indications for use for total hip arthroplasty with stems include:

- Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and,
- Nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of the Anato Hip Stem with compatible Howmedica Osteonics Constrained Liners:

- When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

The Anato Hip Stem is intended for cementless use only and is intended for total and hemiarthroplasty procedures.

Summary of Technological Characteristics:

Device comparisons show that the Stryker Orthopaedics Acetabular Shells, Femoral Stems and Total Hip Instruments for use with the Direct Superior Approach is substantially equivalent to its predicates in terms of intended use, indications, design, materials, performance characteristics and operational principles. The intended use and indications for implants used with the Direct Superior Approach are identical to the intended use and indications of the cleared Trident PSL Shell (K983382), Trident Porous Titanium Acetabular Shell (K010170), Trident Hemispherical Shells (K013676), Tritanium Acetabular Shell System (K081171), Accolade II Femoral Stem

(K120578), Secur-Fit Advanced Hip Stem (K122853) and Anato Hip Stem (K123604), used with the Total Hip Instruments. The materials, design features and functionality for Stryker Orthopaedics Acetabular Shells, Femoral Stems and Total Hip Instruments are substantially equivalent to the previously, cleared predicate devices. The fundamental scientific technology of the modified device has not changed relative to the predicate devices.

The material and design of the Total Hip Surgery Instruments for use with the Direct Superior approach are identical to those of the predicate devices cleared for use with the Posterolateral Approach and Direct Anterior Approach. The operational principles of the Total Hip Surgery Instruments are similar to those of the predicate devices.

Non-Clinical Testing: Performance testing was not required in support of this submission because this submission covers a labeling modification to introduce an additional surgical protocol, Direct Superior Approach.

Clinical Testing: Clinical testing was not required as a basis for substantial equivalence.

Conclusion: The Stryker Orthopaedics Acetabular Shells, Femoral Stems and Total Hip Instruments for use with the Direct Superior Approach are substantially equivalent to the predicate devices identified in this premarket notification.